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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,319	11/02/2000	Hiroo Kumagai	1514-00	4918

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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/704,319	KUMAGAI ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 9/9/02, has been entered into the record. Claims 1-11 were pending in this application. Claims 5 and 7-11 have been cancelled. Therefore, claims 1-4 and 6 are pending and are the subject of this Office Action.

B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

A. The objection to the title has been withdrawn since Applicants have amended the title to recite that the invention is drawn toward a method of examining opioid involvement in pruritis.

B. The objection to the specification regarding grammatical errors has been withdrawn in view of Applicants' amendments to the disclosure.

3. Claim Objections

A. Claim 6 is objected to since the word "scbies" is missing an "a."

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Applicants have amended the claims to limit the examined condition to pruritic diseases as requested by the Examiner on pages 3-4 of the Office Action dated 4/9/02. The Examiner apologizes for this suggestion, but upon further consideration, the specification is not enabled for methods of examining all pruritic diseases. The following rejection is, therefore, made.

Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for examining pruritis in a patient undergoing hemodialysis comprising measuring the concentration of opioid peptides to determine whether opioids are involved in the disease, does not reasonably provide enablement for a method for examining any and all pruritic diseases in a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of

experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive regarding Applicants claiming a method for examining **any and all pruritic diseases** in a patient comprising measuring the concentration of opioid peptides. Applicants have only demonstrated that opioid receptors, and their peptides, are involved in pruritis associated with hemodialysis and Applicants have only provided guidance and working examples that pruritis may be linked to imbalances of various opioid peptides, or opioid receptors, in the body. Furthermore, Applicants have only demonstrated that mu and kappa opioid receptors are linked to hemodialysis-associated pruritis, and no tests have been performed, or data shown, which relates the role of delta opioid receptor expression to this disease.

However, Applicants are claiming that they can determine whether opioid peptides are involved in *any and all* pruritic diseases. Applicants provide no guidance or working examples for determining whether opioid peptides, are involved in diseases other than hemodialysis-associated pruritis. It is possible that opioid peptides can be upregulated or downregulated in a patient for reasons not linked to the disease being studied. For example, a patient may have a genetic cause of altered peptide levels unassociated with pruritis, or, more specifically, hemodialysis. Similarly, the patient may have altered levels of opioid peptides due to a condition unrelated to the disease being studied. Applicants have not taught the artisan how to conclude that opioid receptors are involved in a particular pruritic disease other than hemodialysis. Therefore, it is not predictable to the artisan how to determine whether opioids are involved with the disease being studied.

Similarly, Applicants have only provided guidance and working examples that 3 opioid peptides, β-endorphin, Leu-enkephalin and dynorphin A, and not the **excessive breadth of claimed opioid peptides** which were obtained **only from peripheral blood** and not from all blood cells, body fluids, or tissues were indicative of itching. Again, the breadth of the claims is excessive with regard to Applicants claiming the ability to determine whether opioids are involved in pruritic diseases by measuring any and all opioid peptides in any blood cell, body fluids, or tissue. Applicants have not enabled the ability to determine if opioids were involved in a disease by measuring, for example, the ratio of opioid peptides in brain tissue, lymph, aqueous humor in the eye, etc, but have only correlated opioids with a disease by measuring very specific peptides in very specific fluids (i.e. peripheral blood). It would be expected that patients with different pruritic diseases, such as those in claim 6, would have different ratios of opioid peptides and Applicants have not taught the artisan how to identify and differentiate the specific pruritic

diseases suffered by a patient simply by measuring the ratio of opioid peptides in the blood sample. In other words, due to this lack of guidance in the specification, simply knowing, for example, a patient's endorphin:dynorphin ratio would not permit the artisan to determine if the patient was suffering from neurodermatitis, contact dermatitis, pregnancy, diabetes, or scabies, etc.

In summary, due to the excessive breadth of the claims for determining whether opioid peptides are involved in diseases other than pruritis, for claiming the ability to determine whether opioids are involved in a disease by measuring any and all opioid peptides in any blood cell, body fluids, or tissue as well as the lack of guidance and working examples of diseases which present with an opioid imbalance other than pruritis and the inability to conclude that opioid peptides, are involved in the disease being studied, along with the unpredictability to the artisan how to determine that altered opioid peptide levels are, in fact, involved in said disease, the Examiner holds that undue experimentation is necessary to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The claims recite methods for examining a pruritic disease by measuring the level of opioid peptides in a patient. However, the specification provides a written description of the identification of only one pruritic-associated disease, hemodialysis. No other diseases (i.e. species) are described, or contemplated, within the instant specification besides the mere mention of various diseases known to be involved with itching. Applicants only provide adequate description of the ratios of opioid peptides in hemodiaysis patients. Therefore, one skilled in the art cannot reasonably visualize or predict the ratios of opioid peptides in other diseases which comprise the genus of pruritic diseases claimed, including those in claim 6 because it is unknown and not described what ratios of opioid peptides are associated with pruritic diseases other than for hemodialysis.

Thus the scope of the claims includes numerous pruritic diseases, and simply knowing an opioid peptide ratio in a patient would not allow the artisan to identify which pruritic disease the aptient is experiencing. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe a means of identifying the specific pruritic diseases from which a patient suffers given only the

knowledge of an opioid peptide ratio, and because the genus is highly variant, "pruritis" alone is insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made; thereby not meeting the written description requirement under 35 USC 112, first paragraph

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1-6 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims.

7. Claim Rejections - 35 USC § 102

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' amendments to the claims.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 21, 2002